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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,739	06/08/2001	John Russell Robertson	02332-0020 49409-264826	9829

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EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 02/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/857,739	ROBERTSON ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2004 and 23 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 52-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 52-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01/20/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/23/2004, and 11/23/2004 has been entered. Applicant's submission of the new abstract, and Dr. Robertson's declaration under 37 CFR § 1.132 is acknowledged.

Claims 1-4, 52-66 are pending and examined on merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

This Office action contains new grounds of rejection.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in United Kingdom on 10 December 1998. It is noted, however, that applicant has not filed a certified copy of the GB9827228.9 application as required by 35 U.S.C. 119(b). This application is a 371 and the Office will try to obtain the GB9827228.9 application through the international bureau responsible for supplying the document.

Claim Rejections - 35 USC § 103, Withdrawn

The rejection of claims 1-4 under 35 U.S.C. 103(a) as being unpatentable over either von Mensdorff-Pouilly et al, Eur J Cancer. 1996 Jul;32A(8):1325-31, or Gourevitch et al, Br J Cancer. 1995 Oct;72(4):934-8 in view of Petrarca et al, Eur J Cancer. 1996 Nov;32A(12):2155-63 is withdrawn because applicant's argument along with the data shown Dr. Robertson's declaration indicates that the monoclonal antibody and autoantibody are not functionally equivalent, thus the claims are not obvious over the art of record.

The Following Are New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 59, and 60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and

8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

This enablement rejection is made because the claims are interpreted as drawn to method of using autoantibodies obtainable from monocytes isolated from a patient with either primary breast cancer or advanced breast cancer.

On-line Medical Dictionary downloaded on 2/5/05 from url..cnacerweb.ncl.ac.uk teaches "monocyte" is mononuclear phagocyte circulating in blood that will later emigrate into tissue and differentiate into a macrophage.

Voet et al., (1990, Biochemistry, pages 1096, and 1098 only) teaches that antibodies are produced by B lymphocytes or B cells, not by monocytes or macrophage. Rather monocytes or macrophages have function other than producing antibodies including autoantibodies. Note middle of Figure 34-13.

The specification doe not disclose how to obtain autoantibodies from monocytes.

Considering the unpredictable state of art, limited guidance, no examples in the specification how to make the autoantibodies from monocytes that do not appear to have antibody producing function, it is concluded that undue experimentation is required to practice the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 52, 53, 54, 62, and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Rao et al., (1987, IDS #3 filed on 01/20/2004, Proceedings of the American Association of Cancer Research Annual Meeting, vol. 28, page 358, #1419).

Claims 1, 3, 4, 52, 53, 54, 62, 63, 64, and 66 are interpreted as drawn to method of detecting a cancer-associated protein marker in a bodily fluid from a human having ovarian cancer using polyclonal autoantibodies obtained from a human.

Rao et al., teach method of detecting a cancer-associated protein marker in a bodily fluid from a human having ovarian cancer using polyclonal autoantibodies obtained from a human using an ELISA assay. As for claim 65, the active steps of the instant claim and those of the art are the same. The intended use of the instantly claimed invention i.e. for therapy consideration is not given patentable weight. The claimed invention is drawn to detect a cancer-associated antigen using the instantly claimed active steps. Thus, Rao et al., anticipate claims 1, 3, 4, 52, 53, 54, 62, and 66.

Claim Rejections - 35 USC § 103

Claims 1, 63, and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rao et al., (cited above) in view of Voet et al., (1990, Biochemistry, page 78 only).

Claims 1, 63, and 64 are interpreted as drawn to method of detecting a cancer-associated protein marker in a bodily fluid from a human having ovarian cancer using polyclonal autoantibodies obtained from a human, wherein the autoantibodies are immobilized on a solid surface.

Rao et al., method of detecting a cancer-associated protein marker in a bodily fluid from a human having ovarian cancer using polyclonal autoantibodies obtained from a human using an ELISA assay with the antigen being immobilized on a solid surface.

Rao et al., do not teach the autoantibodies are immobilized on a solid surface.

However, Voet et al., teach immobilizing an antibody on a solid surface had been well known in the art before the effective filing date of the instant application.

Therefore it would have been obvious to immobilize autoantibodies instead of antigen being immobilized. This would have been accomplished with a reasonable expectation of success.

Claims 1, and 63-65 are rejected under **35 U.S.C. 103(a)** as being unpatentable over Rao et al., (cited above) in view of Voet et al., (1990, Biochemistry, page 78 only) further in view of US 5157020 A (1992).

The claims 1, and 63-65 are interpreted as drawn to method of detecting an amount of a cancer-associated protein marker in a bodily fluid from a human having ovarian cancer using polyclonal autoantibodies obtained from a human, wherein the autoantibodies are immobilized on a solid surface, wherein the amount is determined by adding a labeled antigen capable of binding to the autoantibodies.

Rao et al., method of detecting a cancer-associated protein marker in a bodily fluid from a human having ovarian cancer using polyclonal autoantibodies obtained from a human using an ELISA assay with the antigen being immobilized on a solid surface.

Voet et al., teach immobilizing an antibody on a solid surface had been well known in the art before the effective filing date of the instant application.

Neither Rao et al., nor Voet et al., teach how to determine the quantity of the antigen being present in the biological sample being tested.

However, US 5157020 A at Fig. 2 teaches an antigen concentration in unknown samples is usually determined by "competitive inhibition assay" by labeled antigen and unlabeled antigen competing for the same antibody. Note the textbook picture explanation by Janeway et al., (Immunobiology downloaded from url.ncbi.nlm.nih.gov/books, total 2 pages) for how competitive inhibition assay is done. Therefore it would have been obvious to use a labeled antigen that could be compete with the cold antigen in a competitive inhibition assay for calculation of amount of the antigen in body fluid. This would have been accomplished with a reasonable expectation of success since this kind of assay is a routine practice in the art as evidenced by 5th edition textbook of Janeway et al.

Claims 1, 2, 55-58, and 61 are rejected under **35 U.S.C. 103(a)** as being unpatentable over Rao et la, (cited above) in view of Gourevitch et al, of record, Br J Cancer. 1995 Oct;72(4):934-8 further in view of Petrarca et al., of record, Eur J Cancer. 1996 Nov;32A(12):2155-63.

The claims are interpreted as drawn to method of detecting a breast cancer-associated protein marker, more specifically MUC-1 (elected species), in a bodily fluid from a human having breast cancer using autoantibodies obtained from a human.

Rao et al., method of detecting a cancer-associated protein marker in a bodily fluid from a human having ovarian cancer using autoantibodies produced by an immortalized cell obtained from a human using an art-known assay of detecting antigen-antibody complex.

Rao et al., do not teach MUC-1 antigen or autoantibodies.

However, Gourevitch et al., teaches presence of circulating MUC-1 in sera of patients from benign to advanced breast cancer with various stages is present. Note abstract, page 936 and Fig. 2 of Gourevitch et al.

Neither Rao et al., nor Gourevitch et al., teach MUC-1 autoantibody.

However, Petrarca et al., teach how to prepare MUC-1 autoantibody produced by an immortalized cell". Petrarca et al., at page 2161, last two paragraphs also teach that the MUC-1 autoantibody is "capable of successfully binding to ...circulating antigen". Therefore, it would have been obvious for one having ordinary skill in the art at the time the claimed invention would to use the MUC-1 autoantibody of Petrarca et al., to detect the circulating MUC-1 antigen in the bodily fluid obtained from breast cancer patient with reasonable expectation of success. It is the Office's position that "substantially asymptomatic for pre-noeplasia" in the instant claim 2 is equivalent to benign breast tumor of Gourevitch et al. Thus, detecting circulating MUC-1 antigen in a bodily fluid of "substantially asymptomatic for pre-noeplasia" would have been accomplished with a reasonable expectation of success.

Conclusion

The art rejection above is made because the Office compares the instantly claimed invention over what the art teaches. In other words, the art rejection is based on comparison between the instant claims to what is known in the art, not the entire disclosure of the instant specification. It is noted that the data in instant specification and also the in Dr. Robertson's declaration indicate that autoantibodies have a higher sensitivities to detect the antigens in a bodily fluid. However, the instant claims as currently construed do not reflect the inventor's discovery, thus not distinguishing over what is known in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey C Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
Art Unit 1642

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
2/7/03